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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte HIROYASU KOKUBO and SAKAE OBARA

Appeal 2009-010550
Application 09/842,466
Technology Center 1600

Decided: April 12, 2010

Before ERIC GRIMES, JEFFREY N. FREDMAN, and
STEPHEN WALSH, *Administrative Patent Judges*.

WALSH, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a coated solid preparation, e.g., a pharmaceutical tablet. The Patent Examiner rejected the claims for obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The invention relates to "film-coated tablets having a pattern of two or more colors." (Spec. 9:6-8.) Claims 6-9, 11, 13-20 and 31-47, which are all the pending claims, are on appeal. Independent claims 31 and 33 read as follows:

31. A solid preparation coated with a multi-colored continuous film coating layer, prepared by the process of

coating a solid preparation with a continuous film coating layer having one or more colorants; and,

exposing a first part of the coating layer to a first amount of radiation and exposing a second part of the coating layer to a second amount of radiation under conditions sufficient to result in the first and second parts of the coating layer having different coloration.

33. A solid preparation coated with a multi-colored continuous film coating layer, prepared by the process of

coating a solid preparation with a continuous film coating layer having one or more colorants; and,

changing the coloration of one or more parts of the coating layer by irradiating those parts of the coating layer to the exclusion of the remainder of the coating.

The Examiner rejected claims 6-9, 11, 13-20 and 31-47 under 35 U.S.C. § 103(a) as unpatentable over Berta[1] and Hogan.[2]

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[1] US 4,820,524, issued to Norbert I. Berta, Apr. 11, 1989.
[2] US 6,406,738 B1, issued to John E. Hogan et al., Jun. 18, 2002.

OBVIOUSNESS

The Issue

The Examiner set out alternative explanations for the conclusion of obviousness. Both explanations rely on interpreting the claims as "product-by-process" claims. The first theory is that the claimed product is the product Berta described, although defined by different words and made by a different process, and that it therefore would have been obvious. (Ans. 3-5.) The second theory is that the claimed product would have been obvious over the combined teachings of Berta and Hogan. (Ans. 5-6.)

Appellants contend that the rejection failed to state a prima facie case of obviousness "because (1) the combination of references fails to teach each and every claim element and (2) because there is no motivation to combine the references" (App. Br. 5), and "the irradiation step of Hogan cannot be applied to the tablet of Berta in a predictable manner" (*id.* at 9).

More specifically, Appellants dispute that the references "disclose or suggest . . . a multi-colored continuous film coating layer." (*Id.* at 5.) According to Appellants: (a) "the coating described in Berta is not a single continuous coating, but rather comprises two separate coatings that are separately applied to each half of the tablet;" and (b) "Hogan teaches a tablet having two separate coatings covering distinct halves of the tablet and does not have the presently claimed multi-colored continuous coating layer." (*Id.* at 6, emphasis deleted.) Further, Appellants contend it was improper for the Examiner to "ignore" the recited process steps (Reply Br. 6), and Hogan does not teach irradiation to form a multicolored continuous coating (*id.*).

The issues are:

did the Examiner err by discounting the recited process steps;

does the evidence support the Examiner's finding that Berta taught or suggested a multi-colored continuous film coating layer;

does the evidence support the Examiner's finding that Hogan taught or suggested a multi-colored continuous film coating layer;

does the evidence support the Examiner's finding that a person of ordinary skill in the art would have been motivated to combine Berta's teachings with Hogan's teachings; and

does the evidence support the Examiner's finding that the Berta and Hogan teachings could be combined with a reasonable expectation of success?

Findings of Fact

1. Berta described capsule-like medicaments having smooth, multi-colored gelatinous coatings. (Berta, col. 4, ll. 31-34.)
2. Berta formed the coating by dipping each end of the medicament in turn into gelatinous material, with the "depth of the dip . . . preferably cam-regulated to the desired capsule size, color scheme and 'seam' requirements." (*Id.* at col. 8, ll. 28-30.)
3. Berta taught: "As indicated in FIGS. 8*a-d*, the color scheme can be bifurcated . . . and a seam . . . can be provided by overlapping the gelatinous coatings on the first and second ends." (*Id.* at col. 8, ll. 30-34.)
4. Berta taught: "Coloring can be added to the coatings to produce opaque or transparent colors such as red, white, pink, green, reddish brown, blue, yellow and black. Colored medicaments are necessary to

give a specialty product a distinctive appearance." (*Id.* at col. 9, ll. 1-7.)

5. Berta taught: "The first and second gelatinous coatings substantially cover the caplet to form a simulated capsule-like medicament with a seam about a transverse axis of the medicament." (*Id.* at col. 10, ll. 38-41.)

6. Hogan described electrostatic powder coating for pharmaceutical tablets. (Hogan, col. 1, ll. 6-19.)

7. Hogan treated the powder with infra red or electromagnetic radiation to form a film coating on the tablet. (*Id.* at col. 4, ll. 32-35.)

8. Hogan taught: "The change in the powder material during the treatment may simply be a physical change from a solid to a liquid and then, on cooling, to a continuous solid film. Alternatively, the powder material may include a polymer which is cured during the treatment, for example by irradiation with energy in the gamma, ultra violet or radio frequency bands, to form a cross-linked polymer." (*Id.* at col. 4, ll. 38-44.)

9. Hogan taught: "Preferably the powder material includes a first component which is fusible to form a continuous film on the surface of the core . . . . The first component may comprise polyethylene glycol which has good fusibility properties and, after treatment, can form a good continuous coat over the surface of the substrate." (*Id.* at col. 7, l. 61 – col. 8, l. 16.)

10. Hogan taught: "Preferably the powder coating material further includes one or more colourants, for example metal oxides or lakes . . . ." (*Id.* at col. 9, ll. 57-58.)

11. Hogan taught: "different coating materials may be used for coating different parts of the core. For example, a different coloured coating may be formed on each of the opposite faces of the tablet." (*Id.* at col. 12, ll. 40-44.)

Principles of Law

"If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985). "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself." *Id.*, quoted in *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1292 (Fed. Cir. 2009) (en banc).

A rejection for obviousness must include "articulated reasoning with some rational underpinning to support the legal conclusion." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007), quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR*, 550 U.S. at 416. "[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *Id.* at 417.

Analysis

The Examiner interpreted the claims on appeal as "product-by-process" claims. We agree. For this kind of claim, patentability is determined by the product, not the process by which the product is made. We therefore reject Appellants' allegation that the Examiner treated the recited process steps improperly.

We first address the case for obviousness based on Berta alone. (Ans. 3-5.) Berta disclosed a multi-colored coating comprising two films meeting at a seam. (FF3.) Berta's use of "seam" in the ordinary sense means that the coating had abutting edges[3] or a joining area of some kind, e.g., an overlap. *See, e.g.*, Berta's Fig. 8a (showing abutting edges) or Fig. 8b (showing overlapping edges). Appellants' film is claimed as "continuous," which has the ordinary meaning "uninterrupted."[4] Because Berta's coating had a seam, it was not continuous in the ordinary sense of the word and the Examiner has provided no reason to interpret the word otherwise. We therefore reverse the rejection based on Berta taken alone.

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[3] seam. (2010). In *Merriam-Webster Online Dictionary*. Retrieved April 1, 2010, from http://www.merriam-webster.com/dictionary/seam:
1 a : the joining of two pieces (as of cloth or leather) by sewing usually near the edge b : the stitching used in such a joining
2 : the space between adjacent planks or strakes of a ship
3 a : a line, groove, or ridge formed by the abutment of edges . . . c : a line left by a cut or wound; . . . .
4 : a weak or vulnerable area or gap <found a seam in the zone defense>

[4] continuous. (2010). In *Merriam-Webster Online Dictionary*. Retrieved April 6, 2010, from http://www.merriam-webster.com/dictionary/continuous:
1 : marked by uninterrupted extension in space, time, or sequence

Turning to the case for obviousness based on combining the teachings of Berta and Hogan, we first agree with the Examiner that a person of ordinary skill in the art would have viewed these references as being in the same field (coated pharmaceutical formulations), and would have thought their teachings were available for combination. The Examiner made thorough findings on the scope and content of Hogan's disclosure. (Ans. 5-6; FF7-11.)

After making those findings, the Examiner concluded: "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the powder coating material methods of Hogan, which comprise the step of employing radiation, within the multi-colored tablet of Berta." (Ans. 6.) According to the Examiner, "[t]he expected result would be an enhanced, multi-colored continuous coating layer having different colors along the body of the tablet for a pleasing colorful appearance for the consumer." (*Id.*) However, claim 31 defines "first and second parts of the coating layer having different coloration," and does not require that the coloration be "along the body of the tablet" as shown in Berta at, e.g. Fig 8*a*. The evidence the Examiner cited was sufficient to show that Hogan alone disclosed the product defined in appealed claims 31 and 33. We agree that the combination of Berta's coloration pattern with Hogan's similar teaching (FF11) would have been obvious, but it was not needed for the prima facie case of obviousness.

Appellants argue that one of skill in the art would not have had "an expectation of success in irradiating the caplets of Berta as taught by Hogan." (Reply Br. 8.) The statement of the rejection did not propose that it would have been obvious to irradiate Berta's caplets. Instead, its focus

was on a product with Berta's color pattern along the body of the tablet. (Ans. 6.) In the "Response to Argument" part of the Answer, the Examiner disagreed with Appellants' argument that irradiating Berta's caplets was pertinent, and emphasized the obviousness of the product, not the process by which it would have been made. (*Id.* at 9-10.) We agree with the Examiner that Appellants' argument is misdirected and unpersuasive.

The dependent claims have not been argued separately and therefore fall with claims 31 and 33. 37 C.F.R. § 41.37(c)(1)(vii).

CONCLUSIONS

The Examiner properly followed "product-by-process" precedent and did not err by basing the patentability determination on the product rather than the process steps.

The evidence does not support the Examiner's finding that Berta alone taught or suggested a continuous film coating layer.

The evidence supports the Examiner's finding that Hogan taught a continuous film coating layer with at least two differently colored parts.

The evidence supports the Examiner's finding that a person of ordinary skill in the art would have been motivated to combine Berta's teachings with Hogan's teachings.

The evidence supports the Examiner's finding that the Berta and Hogan teachings could be combined with a reasonable expectation of success.

SUMMARY

We affirm the rejection of claims 6-9, 11, 13-20 and 31-47 under 35 U.S.C. § 103(a) as unpatentable over the combined teachings of Berta and Hogan.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

cdc

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